Association Bulletin #10-03 - Chronic Fatigue Syndrome and Blood Donation

Date:	June 18, 2010
To:	AABB Members
From:	Jacquelyn Fredrick, MBA, MT(ASCP)SBB – President Karen Shoos Lipton, JD – Chief Executive Officer
Re:	Chronic Fatigue Syndrome and Blood Donation

Summary:

The AABB Board of Directors has approved an interim measure recommended by the AABB Interorganizational Task Force on Xenotropic Murine Leukemia Virus-Related Virus (XMRV) intended to prevent patients with a current or past diagnosis of chronic fatigue syndrome (CFS) from donating blood or blood components. The Task Force recommended that, through the use of donor information materials available at the donation site, blood collectors actively discourage potential donors who have been diagnosed by a physician with CFS [also known as chronic fatigue and immune dysfunction syndrome (CFIDS) or myalgic encephalomyelitis (ME)] from donating blood.[1,2]

Association Bulletins, which are approved for distribution by the AABB Board of Directors, may include announcements of standards or requirements for accreditation, recommendations on emerging trends or best practices, and/or pertinent information. This bulletin contains information, educational resources, and recommendations.

Background:

Evidence of human infection with XMRV was first reported in 2006 in a cohort of US men with localized prostate cancer undergoing radical prostatectomy. Subsequent studies have differed about the association of XMRV and prostate cancer.[4,5]

In October 2009, the journal *Science* published an article reporting that proviral DNA sequences of XMRV were identified in the blood cells of two-thirds of 101 patients in a cohort diagnosed with CFS and in 3.7% of 218 healthy controls. These findings raised concerns about a possible pathologic role of XMRV in CFS. In contrast, XMRV was not detected in two independent studies of 186 and 170 clinically well-characterized symptomatic CFS patients in the United Kingdom, nor in a Dutch study of 32 CFS patients and 43 controls.[7]

Further research efforts to study XMRV, including a protocol by the US Department of Health and Human Services (HHS) Blood XMRV Scientific Research Working Group to evaluate different existing assays for their ability to detect XMRV, are now under way. Unfortunately, definitive answers to the level of risk of transmission of XMRV by individuals with CFS and, to a lesser extent, individuals who have had prostate cancer, are not yet available.

As a result of the publication of the initial *Science* article, AABB convened the Interorganizational Task Force on XMRV in December 2009 with the following charges:

1. Review the available data on XMRV.
2. Make recommendations for further action to assess risk and, if necessary, risk mitigation of transmission of XMRV through blood and blood components.

   Develop appropriate messaging to donors, recipients, and the public on the risk of XMRV transmission through blood and blood components.

The Task Force includes representatives from the blood community, patient advocacy representatives, XMRV subject matter experts, and liaisons from government agencies.

Recent Activity:

Recently, the Canadian Blood Services, Australian Red Cross, and New Zealand Blood Services each announced changes in their respective blood donor deferral policies to indefinitely defer all potential donors who upon presenting for blood donation volunteer that they have a history of CFS in response to general health questioning. These individuals will be indefinitely deferred regardless of whether or not they have active CFS on the day they present for donation.

In May 2010, the HHS Chronic Fatigue Syndrome Advisory Committee (CFSAC) recommended to the Assistant Secretary for Health that blood collection facilities indefinitely defer donors with a history of CFS, or with active CFS, through a donor screening question specifically for CFS.

The CFIDS Association of America explicitly advises individuals with CFS that they should not donate blood or organs. On May 18, 2010, the CFIDS Association of America Board of Directors affirmed the following guidance to the CFS patient community:

> The CFIDS Association of America reiterates its long-standing recommendation urging that individuals with CFS voluntarily not donate blood or organs. This recommendation is based on issues of blood donor safety and blood recipient safety. Research has demonstrated that orthostatic intolerance, low blood volume, and infections are common in CFS. Until more is known about the role of various infectious agents in CFS, it is prudent for individuals with a past or present diagnosis of CFS to refrain from giving blood and donating organs to protect the safety of the blood and transplant organ supply for all recipients.[8]

Currently, there are insufficient data to confirm or refute the potential transmissibility of XMRV through blood transfusion or the relationship of the virus to any disease or syndrome. Background information regarding XMRV can be found in the AABB XMRV Fact Sheet, published in January 2010,[9] as an addition to the 68 fact sheets on emerging infectious disease agents prepared by the AABB Transfusion Transmitted Diseases Committee and published in the

August 2009 Supplement to *Transfusion*. According to the Committee's risk priority assessment, XMRV was categorized as a "yellow" agent, corresponding with "absent to low scientific/epidemiologic evidence of risk regarding blood safety for which there is public and/or regulatory concern."[10] However, definitive answers about the transmissibility of XMRV through blood transfusion will not be available for some time.

Recommendation:

As an interim measure, and until further definitive data are available, AABB recommends that blood collecting organizations make educational information available regarding the reasons why an individual diagnosed with CFS should not donate blood or blood components. The data currently available from those studies reporting positive results suggest a lower prevalence of XMRV in prostate cancer than in CFS. There is no recommendation to change the deferral criteria for potential blood donors with a history of prostate cancer who should continue to be evaluated according to current donor criteria relating to a history of cancer.

The AABB Task Force has developed materials that blood collecting organizations may wish to utilize as provided or alter to better conform to the needs of its donor population. The resources provided include the following and can be accessed on the AABB website www.aabb.org.

- A statement that blood collecting organizations can make available to potential donors in the form of a poster or handout, which requests that individuals diagnosed with CFS by their physician not donate.
- An educational handout that blood collecting organizations can make available to potential donors who request more information regarding why those with CFS should not donate.

Conclusion:

The AABB Board of Directors and the AABB Interorganizational Task Force on XMRV will continue to monitor activity and research associated with XMRV and, as appropriate, will provide further communication and guidance to the blood banking and transfusion medicine community.

References:

[1] What you should know about chronic fatigue syndrome and blood donation. Bethesda, MD: AABB, 2010.

[2] CFS and blood donation statement. Bethesda, MD: AABB, 2010.

[3] Silverman RH, Nguyen C, Weight CJ, Klein EA.The human retrovirus XMRV in prostate cancer and chronic fatigue syndrome. doi:10.1038/nrurol.2010.77. Nat Rev Urol Epub 2010 Jun 1.

[4] Groom HT, Boucherit VC, Makison K, et al. Absence of xenotropic murine leukaemia virus-related virus in UK patients with chronic fatigue syndrome. Retrovirology 2010;7:10. [Available at http://www.retrovirology.com/content/7/1/10.]

[5] Van Kuppeveld FJ, de Jong AS, Lanke KH, et al. Prevalence of xenotropic murine leukaemia virus-related virus in patients with chronic fatigue syndrome in the Netherlands: Retrospective analysis of samples from an established cohort. Br Med J Epub 2010 Feb 25.

[6] Lombardi VC, Ruscetti FW, Das Gupta J, et al. Detection of an infectious retrovirus, XMRV, in blood cells of patients with chronic fatigue syndrome. Science 2009;326:585-9.

[7] Erlwein O, Kaye S, McClure MO, et al. Failure to detect the novel retrovirus XMRV in chronic fatigue syndrome. PLoS ONE 2010;5:e8519.

[8] Guidance for persons with CFS for safe blood donation. Charlotte, NC: CFIDS Association of America, 2009. [Available at: http://www.cfids.org/blood.asp (updated May 21, 2010).]

[9] XMRV fact sheet. Bethesda, MD: AABB, 2010. [Available at: http://www.aabb.org/resources/bct/eid/Documents/xmrvfactsheet.pdf.]

[10] Priority assessment (Appendix 1). In: Stramer S, Hollinger BF, Katz LM, et al. Emerging infectious disease agents and their potential threat to transfusion safety. Transfusion 2009;49(Suppl):30S-44S.

